

## **REMARKS**

Applicants wish to thank the Examiner for reviewing the present patent application. The present comments are consistent with those filed under 37 CFR §1.116 and responsive to the Advisory Action.

### **I. Rejection Under 35 USC §103**

The Examiner has maintained the rejection of claims 1, 2, 5-6, and 9 under 35 USC §103 as being unpatentable over Granger et al., U.S. Patent No. 5,723,139 (hereinafter, '139) and Fisher et al., U.S. Patent No. 6,365,630 (hereinafter, '630) in view of Liu et al., U.S. Patent No. 5,976,555 (hereinafter, '555) and Soares et al., U.S. Patent No. 5,941,116 (hereinafter, '166). In the rejection, the Examiner mentioned, in summary, that the '139 reference discloses a skin conditioning composition comprising retinal or retinyl ester in an amount from about 0.001% to about 10% in combination with a retinoid booster, polycyclic terterpene carboxylic acid and glycyrrhetic acid in an amount of from about 0.0001% to about 50%. Moreover, the Examiner noted and maintained that the '139 reference fails to disclose a composition with phytoestrogens and a dual compartment system. The Examiner continued by mentioning that the '630 reference describes skin care compositions containing retinoic acid and phytoestrogens such as genistein. The Examiner further continued by maintaining that the '555 reference teaches that retinoids such as retinal and retinyl ester in skin care compositions are unstable due to oxidation or isomerization to non-efficacious chemical forms, and further teaches that several stable compositions for skin care can be supplied in two bottles separating retinoids from other ingredients. Finally, the

Examiner relied on the '116 reference and again maintained that the same describes skin compositions in separate containers.

In view of this, the Examiner continues to maintain that one of ordinary skill in the art would have found it obvious at the time the invention was made to employ two compartments, the first one for storing retinoids and the second one for storing retinoid booster and a phytoestrogen to keep retinoids from reacting with its booster in order to preserve the stability of retinoids and avoid chemical degradation prior to use. Thus, the Examiner, again, believes that the rejection made under 35 USC §103 is warranted.

Notwithstanding the Examiner's apparent position to the contrary, it is, again, the Applicants' position that the presently claimed invention is patentably distinguishable from the above-described for at least the following reasons.

Again, as already made of record, the present invention, as set forth in independent claim 1 as presented, is directed to a stable skin care product containing a first composition comprising about 0.001% to about 10% of a retinoid; and a second composition comprising about 0.0001% to about 50% of at least one retinoid booster selected from the group consisting of arachidic acid, myristic acid, azelaic acid, carboxylic acid, glycolic acid, lactic acid, salicylic acid, and mixtures thereof, and from about 0.001% to about 10% of at least one phytoestrogen selected from the group consisting of genistein, daidzein, glycitin, biochanin A, formononetin, equol, and mixtures thereof, a first compartment for storing the first composition and a second compartment for storing the second composition whereby the first and second compartments are joined together.

Independent claim 1 has now been amended such that the stable skin care product is now defined to be one suitable to treat acne, wrinkles, psoriasis, age spots or discoloration on skin.

The invention of claim 1, again, is further defined by the dependent claims which claim, among other things, that two retinoid boosters may be used in an amount from about 0.0001% to about 50% in the second composition.

Independent claim 5 as presented is directed to a stable skin care product containing a first composition and a second composition wherein the first composition comprises from about 0.001% to about 10% of a retinoid to provide a first benefit, and the second composition comprising from about 0.0001% to about 50% of at least one retinoid booster selected from the group consisting of vanillin, arachidic acid, linoleic acid, myristic acid, amsacrine, carbenoxolone, glycyrrhetic acid, phosphatidyl ethanolamine, sphingomyelin, phosphatidylcholine, and mixtures thereof; and about 0.001% to about 10% of at least one phytoestrogen selected from the group consisting of genistein, diadzein, glycitin, biochanin A, formononetin, equol, and mixtures thereof, the booster and phytoestrogen boosting the first benefit; a first compartment for storing the first composition; and a second compartment for storing the second composition, the first and second compartments being joined together.

Independent claim 5 has been amended such that the stable skin care product is now defined to be one suitable to treat acne, wrinkles, psoriasis, age spots or discoloration on the skin.

The invention of claim 5, again, is further defined by the dependent claims which claim, among other things, that the second composition can have at least two retinoid

boosters in an amount of from about 0.0001% to about 50%, and that the retinoid booster may be selected from the group consisting of glycyrrhetic acid, phosphatidylcholine, and mixtures thereof.

The independent claims have been amended such that the booster is one suitable to potentiate the action of the retinoid and inhibit retinoic acid degradation.

New claims 11 and 12 describe a method for treating skin.

In contrast, and as already made of record the '139 reference is merely directed to a skin care composition having a polycyclic triterpene carboxylic acid and a retinoid. The '139 reference does not teach or suggest, even remotely, the use of the claimed phytoestrogens. Moreover, the '139 reference does not teach or suggest the storage of a first composition comprising retinoid and a second composition comprising retinoid booster, and phytoestrogens in a separate compartment that is joined with a compartment holding the first composition. In an attempt to cure the vast deficiencies of the primary reference, the Examiner continues to rely on the '630 reference. The '630 reference, however, merely describes compositions for ameliorating various effects of UVA and UVB radiation from the sun. The '555 reference, again, discloses a skin care composition having an oil-in-water emulsion base containing retinoids and possessing good physical and chemical stability. It has been reported in the '555 reference that the use of retinoids in topical compositions are unstable and can either oxidize or isomerize to non-efficacious chemical forms resulting in an amount of retinoid which is so low it is unacceptable to provide a benefit. The attempts made to stabilize the retinoid in the '555 reference require a complex oil-in-water emulsion system for stabilization wherein the stabilizing system is one which requires, for example, oil-soluble antioxidants, chelating agents, or chelating agents and oil soluble antioxidants,

or chelating agents and an antioxidant present in each of the oil and water phases of the emulsion. There is no teaching whatsoever in the '555 reference that even remotely suggests the combination of specific retinoids with specific boosters and phytoestrogens as claimed in the present invention whereby the booster potentiates the action of the retinoid and inhibits degradation of retinoic acid. The two component system as claimed in this invention, as well as the two preferred boosters as claimed in this invention are not even remotely suggested by the '555 reference which, again, employs a complicated oil-in-water emulsion system to stabilize certain retinoids. Finally, the '116 reference, again, teaches away from the presently claimed invention. Again, and as already made of record, the '116 reference merely describes a method for a skin treatment regime wherein a first and second composition are stored in separate containers and only connected to each other to remind the consumer to use the compositions in tandem and to facilitate in one sale all necessary elements of a suggested regime. Thus, the '116 reference clearly teaches away from the present invention and cures none of the vast deficiencies of the primary reference since it discloses two separate containers for separating two different skin actives for two different benefits. Moreover, the reference fails to even remotely teach, suggest or disclose the need to separate phytoestrogens from retinoids. The present invention, again, is directed to two separate compositions with one intended to boost the benefit of the other. Again, according to the present invention, the two compositions are intended to be applied simultaneously or consecutively, but are kept separately for stability reasons. The presently claimed invention clearly conveys that the specified retinoids and the phytoestrogens, although separated into two compartments, are there for the same benefit. The first composition provides a benefit to the skin while the second composition works to boost or enhance the effect of the first composition. Again, the '116 reference teaches away from the present invention and fails to provide any

suggestion or motivation for the particular way the compositions of the present invention are stored separately.

In the Advisory Action, the Examiner concludes that the '139, '555 and the '116 references support the rejection under 35 USC §103 for the reasons set forth above. Applicants respectfully disagree.

The storage of the compositions in separate containers as set forth in the presently claimed invention is novel and unobvious. None of the references relied on by the Examiner, even remotely, teach all the important and critical limitations set forth in the presently claimed invention as now presented. Since the Examiner has not established a *prima facie* case of obviousness as required under 35 USC §103, Applicants again request that the obviousness rejection made to claims 1, 2, 5-6 and 9 be withdrawn and rendered moot so that the extreme expense of an appeal may be avoided.

## II. Rejection Under 35 USC §103

The Examiner continues to maintain the rejection of claims 1, 2, 5, 6 and 10 under 35 USC §103 as being unpatentable over Granger et al., U.S. Patent No. 5,723,139 (hereinafter, '139) and Fisher et al., U.S. Patent No. 6,365,630 (hereinafter, '630) and Maybeck, FR 2 777 179 (hereinafter, '179) in view of Liu et al., U.S. Patent No. 5,976,555 (hereinafter, '555) and Soares et al., U.S. Patent No. 5,914,116 (hereinafter, '116). The Examiner maintains such rejection in the Advisory Action.

For the reasons already made of record above, the '139 reference is directed to skin care compositions with polycyclic triterpene carboxylic acid and a retinoid. The '139 reference does not, even remotely, teach or suggest the claimed phytoestrogens. Moreover, the '139 reference does not teach or suggest the storage of a first composition comprising retinoid and a second composition comprising retinoid booster and phytoestrogens in a separate compartment whereby the two compartments are joined together.

As already made of record, the '630 reference is merely directed to a ameliorating effects of UVA and UVB radiation from the sun. Again, simply because the '179 reference appears to disclose the phosphatidylcholine and glycyrrhetic acid somewhere in its disclosure clearly does not make it obvious for one of ordinary skill in the art to combine these materials with retinoids and with retinoid boosters in a dual compartment package and to come up with the present invention. The Examiner, again, is not allowed to pick and choose elements from numerous references without there being motivation to combine the same. Furthermore, and as already made of record, the '555 reference is merely directed to the use of a complex oil-in-water emulsion comprising a specifically defined stabilizing system to stabilize certain retinoids. It has nothing to do with a dual compartment system as claimed in the present invention. Finally, and again, the '116 reference is directed to a treatment regime for skin that employs two different compositions that are to be used for two different benefits. The two different compositions have two different skin actives and they are stored in two separate containers. Again, the present invention is directed to two separate compositions with one intended to boost the other. As amended, the booster is present to potentiate the action of the retinoid and inhibit degradation of retinoic acid.

Such an arrangement of compositions allows for effective treatment of skin characteristics.

Based on the above, it is clear that all the important and critical limitations set forth in the presently claimed invention are not found in the combination of references relied on by the Examiner. In view of this, Applicants respectfully submit that a *prima facie* case of obviousness has not been established and the rejection made under 35 USC §103 should be withdrawn and rendered moot.

Regarding the Examiner's response to the prior arguments in the Advisory Action, it is respectfully submitted, again, that that '116 reference describes a product having two compositions that impart two benefits. The reference does not, for the reasons of record, render the claimed invention (as presented) obvious.

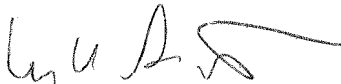
Applicants submit that all claims of record, as now presented, are now in condition for allowance. Reconsideration and favorable action are earnestly solicited.

In the event the Examiner has any questions concerning the present patent application, the Examiner is kindly invited to contact the undersigned at his or her earliest convenience.



In view of the foregoing amendment and comments, applicants request the Examiner to reconsider the rejection and now allow the claims.

Respectfully submitted,



---

Edward A. Squillante, Jr.  
Registration No. 38,319  
Attorney for Applicant(s)

EAS/pod  
(201) 894-2925